

REMARKS**Affirmation of Provisional Election**

Applicants affirm that the claims of Group I were elected for further prosecution and claims 37-57 were withdrawn. Claims 59 and 61-62 are cancelled herein.

Rejections of Claims and Traversal Thereof

In the December 30, 2005 Office Action:

claims 1-3, 5-9, 10-12, 14-18, 19-21, 23-27, 28-30, 32-36 and 58 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855);

claims 4, 13, 22 and 31 were rejected under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855) and further in view of Leung, et al. (U.S. Patent No. 6,599,310); and

claims 58 and 60 were rejected on the grounds of judicially created nonstatutory obviousness-type double patenting as being unpatentable over claim 16 and 22, respectively, of copending Application No. 10/065280.

These rejections are hereby traversed, and reconsideration of the patentability of the pending claims herein is requested, in light of the ensuing remarks.

Rejections under 35 U.S.C. §102(b)/ 35 U.S.C. §103(a)

Claims 1-3, 5-9, 10-12, 14-18, 19-21, 23-27, 28-30, 32-36 and 58 were rejected under 35 U.S.C. §102(b) as being anticipated by or in the alternative, under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855). Applicants submit that Buncke does not anticipate or render obvious the presently claimed invention.

Broadly, applicants' claimed invention includes a barbed suture for connecting human or animal tissue, comprising

(a) an elongated body having a first end and a second end and a diameter and
(b) a plurality of barbs projecting from the body, each barb facing in a direction and being adapted for resisting movement of the suture, when in tissue, in an opposite direction from the direction in which the barb faces, wherein the barbs have a configuration comprising:

- (i) a barb cut angle Θ ranging from about 140° to about 175° (claim 1),
- (ii) a barb cut depth where the ratio of the barb cut depth to the suture diameter ranges from about 0.05 to about 0.6 (claim 10),
- (iii) a barb cut length where the ratio of the barb cut length to the suture diameter ranges from about 0.2 to about 2 (claim 19), or
- (iv) a barb cut distance where the ratio of the barb cut distance to the suture diameter ranges from about 0.1 to about 6 (claim 28).

According to the Office, the presently claimed sutures are disclosed in Buncke. Applicants vigorously disagree. It is well settled in the law that to constitute anticipation, a single prior art reference must disclose each and every material element of the claim. *In re Marshall*, 198, USPQ 344, 346 (CCPA 1978). The sutures described by Buncke fail to meet this standard. The Buncke reference describes barbed sutures having suture diameter ranging from 100 microns to 500 microns, the spacing of the barbs from 100 microns to 1 mm, and the depth of the barb cut in the suture ranging from 30 micron to 100 microns. (See Buncke at column 8, lines 14-19).

The Office admits that the reference provides no disclosure relating to barb cut angle- Θ or length of barb cut into the suture at any angle. However, the Office states that it would have been obvious to a person of ordinary skill in the art to derive the barb cut angle or the ratio of barb cut length to suture diameter from the depth and spacings parameters given by Buncke. Applicants disagree because the Buncke reference provides no teaching or suggestion for the barb cut angle or the length of the cut relative to that specific angle. Where in the cited reference is there any disclosure that provides a correlation between the distance between barbs and the depth cut of the barb that provides guidance for a barb cut angle or the length of such cut? Clearly, there is none.

The barb spacing of the Buncke's barbs can range from 100 micron to 1 mm and this information in combination with the depth of the barb cut provides no guidance for a barb cut angle ranging from about 140 to 175 degrees or a ratio of the barb cut length to the suture diameter ranging

from about 0.2 to about 2. The barb spacing as disclosed by Buncke simply does not relate to the claimed barb parameters, which are directed to characteristics of an individual barb.

The Office's position in essence is that applicants have done nothing more than use routine experimentation to optimize the barb cut angle or length of barb cut. However, conspicuously missing from the record is any substantive evidence that one of ordinary skill in the art would have been motivated to make the modifications of the prior art and to select the specific barb cut angles or length of barb to arrive at applicants' claimed invention. Further, the Office has neglected to show any teaching or suggestion as to why one would choose applicants' claimed barb cut angles or length of cut from the multiplicity of all possible choices. As the Court pointed out in *In re Kratz*, 201 U.S.P.Q. 71 (C.C.P.A. 1979), "[e]ven if the bare lists of components found ...were in the prior art, those extensive lists are quite mute in directing one having ordinary skill in the art to any particular compound for any purpose." The Court in *Kratz* reversed the Examiner's rejection for obviousness, and stated that "for there to be a denial of patentability the prior art itself [should] further provide some foreseeability or predictability that the compound is a significant...ingredient." Consistent with such standard, there is a complete lack of any predictability in Buncke as to what barb cut angles or length of barb cut are effective in increasing the strength of the closure.

Applicants further argue that this rejection amounts to the application of an "obvious to try" standard which is known to be an improper standard for a §103 rejection. The Office contends that because the cited reference discusses barb cut spacing and depth of barb cut that there is sufficient teachings or suggestions to render the claimed invention as obvious.

The Board decision in *Ex parte Obukowicz*, 27 USPQ 2d 1063, 1065 (B.P.A.I.) (citing *In re O'Farrell*, 853 F.2d 894, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988)) is instructive and relative to the statements made by the Office. In *Obukowicz* the invention concerned incorporating a DNA sequence, for a substance toxic to plant pests, directly into the genetic code of bacteria. The bacteria were then applied to plants whereon the bacteria produced and extruded the toxic substance, which in turn was consumed by the plant pests. The examiner initially rejected the claimed invention because a prior art reference mentioned combating mosquitoes using genetically engineered bacteria such as "natural pond microflora." However, the Board ruled that the mere mention of "natural pond microflora" was insufficient to provide the necessary suggestion of modification. As stated by the Board:

"the statement (in prior art) is but an invitation to scientists to explore a new technology that seems a promising field of experimentation. The Dean statement is of the type that gives only general guidance and is not at all specific as to the particular form of the claimed invention and how to achieve it. Such a suggestion may make an approach "obvious to try" but it does not make the invention obvious."

Likewise, in the present instance, a general statement about the depth of a barb cut or the distance between barbs in the Buncke reference, without any additional guidance, is not sufficient to meet the Office's burden of establishing a *prima facie* case of obviousness. As such, independent claims 1, 19, and all claims depending therefrom are not anticipated or rendered obvious by the Buncke reference.

According to the Office, independent claims 10, 28 and claims depending therefrom are disclosed in the Buncke reference. As discussed above, claim 10 of the presently claimed invention recites a barb cut depth (D:SD) with a ratio of the barb cut depth (D) to the suture diameter (SD) that ranges from about 0.05 to about 0.6; and claim 28 recites a barb suture comprising a barb cut distance (P:SD) with ratio of the barb cut distance (P) to the suture diameter (SD) that ranges from about 0.1 to about 6.

In contrast, as set forth above, the Buncke reference discloses a barb cut depth from about 30 microns to 100 microns, a spacing between barbs from about 100 micron to 1 mm. and a suture diameter of from about 100 microns to 500 microns. Notably, the Buncke reference **does not disclose a ratio of any type and the disclosure is completely devoid of any mention of a ratio.** Anticipation under 35 U.S.C. § 102 requires the presence, in a single reference, of each and every element of the claimed invention, **arranged as in the claim.** *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984). Buncke merely discloses a broad genus of possible structural configurations with ranges of dimensions. Where in the Buncke reference is there disclosure relating to a ratio? Further, it is well settled in the law and set forth in the MPEP that when the claimed elements are not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, anticipation can only be found if the specific elements (ratios) are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). (MPEP 2131.03). Clearly, the only way the ratios of the present invention (barb cut depth:diameter of suture (D:SD) and spacing between barbs:diameter of suture (P:SD)) can be determined from the disclosure of Buncke is to piece

together separate values from the broad disclosed ranges and combine them. Applicants' claimed ratios are not sufficiently limited or well delineated by Buncke, nor are all necessary parameters disclosed and, as such, the disclosure of Buncke does not meet the requirements of an anticipatory reference.

Moreover, even if ratios were disclosed by Buncke, which of course they are not, the wide ranges for suture diameter, barb depth cut and distance between barbs provides no guidance to go in the directions of applicants' claimed invention. In the present matter, one skilled in the art reading Buncke would have to pick one value of the suture diameter and a value of the barb depth cut or distance between barbs from the multiplicities of values given by Buncke, without any guidance from Buncke and attempt to recreate applicants' claimed invention. Moreover, disclosure of barb cut depth will not suggest barb cut distance without disclosure of cut angle. Therefore, Buncke is missing an important parameter which is necessary to disclose or suggest the claimed invention. Clearly, from the range of possible values for the suture diameter, the barb depth cut and distance, finding an anticipatory value or range for the ratios set forth in the presently claimed invention would be the same as discovering the combination of a safe by an inspection of its dials, *Ex parte Garvey*, 41 USPQ 583 (POBA 1939). Applicants insist that the Buncke reference does not qualify as an anticipatory reference under 35 U.S.C. §102.

Further, the Buncke reference does not render obvious the recited subject matter of independent claims 10 and 28 and all claims depending therefrom. As stated above, the Buncke reference does not disclose, teach or suggest any of the presently claimed ratios or the angles of barb cuts and there is no suggestion to go in that direction. Clearly, that which is unknown cannot be obvious.

It is incumbent on the Office to provide some suggestion or teaching in the prior art that would lead one skilled in the art to proceed in the direction of applicants' claimed invention. What is the asserted motivation put forth in the Buncke reference to fabricate barbed sutures having a barb cut depth with a ratio of the barb cut depth to the suture diameter of 0.05 to about 0.6 or a barb cut distance with a ratio of the barb cut distance to suture diameter of from about 0.1 to about 6? The Courts have addressed this issue numerous times and have stated that "[t]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." *In re Mills*, 16 U.S.P.Q.2d 1430

(Fed. Cir. 1990). Thus, this allegedly "obvious" direction is supported only by the Office's reinterpretation of the art in light of applicants' disclosure.

In light of the above discussion and the fact that each and every recited limitation of applicants' claimed invention is not disclosed or suggested in the cited reference, the Office has failed to establish a *prima facie* case of obviousness and applicants request the withdrawal of the rejections of claims 1-3, 5-12, 14-21, 23-30, 32-36 and 58 under both 35 U.S.C. §102(b) and §103(a).

Rejection under 35 U.S.C. §103(a)

Claims 4, 13, 22 and 31 were rejected under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855) and further in view of Leung, et al. (U.S. Patent No. 6,599,310).

Applicants respectfully point out that under 35 USC §103(c), subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title shall not preclude patentability under this section [section 103 obviousness rejections] where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

At the time that the presently claimed invention was made, it and the '310 patent to Leung et al. were owned by and also subject to an obligation of assignment to the same person, Quill Medical, Inc.

Accordingly, the Examiner is respectfully requested to remove the obviousness rejection based on Buncke in view of Leung et al.

Rejection under Judicially Created Doctrine of Obviousness-Type Double Patenting

Claims 58 and 60 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16 and 22, respectively, of copending application No. 10/065,280. Applicants traverse this double patenting rejection. In any case, until the only remaining rejection is the obvious-type double patenting, applicants will delay filing a terminal disclaimer.

Fees Payable and Petition for Extension of Time

Applicants petition for a three month extension thereby extending the time to respond to the December 30, 2005 Office Action from March 30, 2006 to June 30, 2006. Entry of this Petition requires the Petition fee of \$1020.00. Applicants have added seventy-eight (78) new dependent claims incurring an additional fee charge of \$3900.00. The U.S. Patent and Trademark Office is hereby authorized to charge the additional claim fee and Petition fee in the amount of \$4920.00 and any additional amount to Deposit Account No. 13-4365 of Moore & Van Allen, PLLC.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Nguyen, reconsider the patentability of all pending claims, in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Nguyen is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,



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